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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,493	02/05/2002	Lorraine E. Pena	C-3528/2/US	1201

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,493	PENA ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-22 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-22 and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Response/Amendment dated 9/24/04

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 3-22, and 24-29 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Barbachyn et al (USPN 5,688,792), Borgulya et al (USPN 5,574,05) Kaplan et al (USPN 4,727,070) and Miyauchi (USPN 4,900,730).

4. Claims 1, and 3-20 are drawn to a composition comprising a, oxazolidinone in the form of a suppository, where the carrier is lipophilic. The claims recite the oxazolidinone's preferred structure. Subsequent claims limit the concentrations and species of the lipophilic carrier and the oxazolidinone. Claims 21, 22 and 24-29 are drawn to method of treating a gram-positive bacterial infection with the composition of claims 1 and 3-22. Subsequent claims limit the dosage regimen of the treatment.

5. Barbachyn et al discloses oxazolidinone antimicrobial compounds. The compounds have an identical structure to the compounds of the present invention (Abstract). The compounds of the reference can be formulated into capsules, dispersed granules and similar pharmaceutical dosage forms (col. 6, lin. 45 – 65). Some of the carriers include lipophilic substances such as waxes, cocoa butter. What is lacking in the reference is an explicit disclosure of a rectal suppository, yet capsules are disclosed. These capsules could be manipulated within the level of skill in the art to be used rectally. It would be within the level of skill in the art to modify a capsule for rectal suppository administration.

6. Borgulya et al discloses a suppository formulation comprising an oxazolidinone antimicrobial agent (Example A). Though the active agent is a differing oxazolinidone agent, a skilled artisan would be able to substitute the compound of Barbachyn into that of Borgulya and expect the suppository to deliver the same antimicrobial effects as intended by Borgulya since the active agents are in the same class of compounds.

7. Kaplan et al discloses a suppository formulation comprising oxazolinidone compounds, where the lipophilic carrier is a hard fat (Example 7). Again the active agent differs from that of the claimed invention, but a skilled artisan would be able to substitute the oxazolidinone of Barbachyn into the formulation with an expectation of success since the compounds are in the same class and are used to a similar end.

8. With regard the to the particle size of the compound, the combination of micronized antibacterial agents, lipophilic carriers in a rectal suppository is well known in the art. Miyauchi discloses a rectal suppository where the active antibacterial agents (which are effective against gram-positive bacterial infections) are micronized from 1 – 50 microns, and dissolved in the hard

fat Witepsol H-15 (col. 5 – 24 – 64; Examples). Though the particles of the reference fall within a wide range, the micronizing of particles is well within the level of one of ordinary skill in the art.

9. The claims also recite that a further antibacterial agent is additionally included in the dosage form that also is effective against gram-positive bacterial infections. Though not explicitly taught by the cited references, it is obvious to combine like compounds. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See* In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). It would have been obvious to combine any of the composition well known in the art to be affective against gram-positive bacterial infections (those taught by Miyauchi for instance), with any of the oxazolidinone compounds of the other cited reference.

10. With this in mind a skilled artisan would have been motivated to combine the teachings and suggestions of the art. A skilled artisan would be motivated to include the compounds of Barbachyn into any of the compositions of Borgulya. A skilled artisan would have included the hard fat of Kaplan. The skilled artisan would have followed the knowledge of micronizing antibacterial agents and combining them with hard fats into rectal suppositories shown in Miyauchi. It also would have been obvious to the artisan to include other antibacterial agents in order to increase the bacterial infection fighting power of the compound. This combination of teachings, compositions and suggestions would result in a rectal suppository comprising a hard fat (Witepsol W or H series), an oxazolidinone (Barbachyn) compound, and a further

antibacterial agent, all of which would be effective in treating or preventing bacterial infections resulting from gram-positive bacteria. A skilled artisan would be motivated to combine these teachings in order to provide a stable composition with effective pharmacokinetics to treat infection. A skilled artisan also would have been motivated by the antibacterial properties of the oxazolidinone compound to use this compound in a method to treat infections rectally including the compound of Barbachyn. It would have been obvious to combine the teachings, and suggestions as described here, at the time of the invention, with an expected result of a rectal suppository effective in treating bacterial infection.

Response to Arguments

11. Applicant's arguments filed 9/29/04 have been fully considered but they are not persuasive. Applicant argues the combination of reference does not disclose an oxazolidone compound in a solid particulate dispersion in an acceptable carrier.

It is the position of the Examiner that the combination obviates the claimed invention and is proper. The Barbachyn reference discloses the oxazolidone compound of claims 1, and 21. The reference teaches that the oxazolidone can be in the form of dispersed granules where the carrier is a lipophilic polymer. The reference also discloses the drug can be delivered in capsules. The reference is silent to a rectal adaptation, yet capsules can be adapted for delivery anywhere. This adaptation is well within the level of skill in the art. This can be seen in Borgulya, which discloses the rectal administration of an oxazolidone compound. Kaplan discloses the specific lipophilic carrier, while Miyauchi establishes the level of skill in the art with regard to particle size of antibacterial agents dispersed in lipophilic carriers such as

Witepsol H-15, and delivered as a rectal suppository. These references establish the level of skill in the art and show that one of ordinary skill would have been able to arrive at the claims of the instant invention. Applicant has yet to provide any unexpected results, resulting from the instant claims and continues to argue against the reference individually. Applicant is reminded that The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). With these things in mind it is the position of the Examiner that it would have been obvious to combine the teachings, and suggestions as described here, at the time of the invention with expected result of a rectal suppository effective for treating bacterial infections of the intestines. For these reason the claims remain obviated.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

THURMAN K. PAGE
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